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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/158,120	09/21/98	JOHNSON L	469201-367

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EXAMINER	
EWOLDT,G	
ART UNIT	**PAPER NUMBER**
1644	9

DATE MAILED: 04/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/158,120	Applicant(s) Johnson, L.S.
	Examiner Gerald Ewoldt	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Sep 21, 1998 and Jan 10, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-4, 6, 7, 10, 13, 21, and 22* is/are pending in the application.

Of the above, claim(s) *10, 13, and 22* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-4, 6, 7, and 21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The paper copy of the sequence listing, filed 1/31/00, has not been entered. A formal amendment requesting the entry of said paper copy of the sequence listing is required.

The CRF has been entered. The STIC has made the following corrections:
Non ASCII "garbage" has been deleted at the end of files.

2. Claims 1-4, 6-7, 10, 13, and 21-22 are pending.

3. Applicant's election of Group I (claims 1-4, 6-7 and 21) in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 10, 13, and 22 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 1-4, 6-7, and 21 are being acted upon.

5. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948. Applicant is reminded to change the Brief Description of the Drawings in accordance with these changes.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(C) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-4, 7, and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 and 29-30 of U.S. Patent No. 5,824,307. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims vary only in scope in that the claimed invention encompasses the sequences of SEQ ID NOS: 31 and 34 of the '307 patent. The antibodies claimed in the '307 patent comprise human-murine antibodies containing murine CDR's against the RSV protein F antigenic site C, and human heavy and light chain constant and variable regions.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that, other than antibodies encoded by SEQ IDS NO:17 and 20 (humanized mAb 1308F) and 31 and 34 (humanized mAb 1129), both of which are specific for site C of the respiratory syncytial virus (RSV) protein F, Applicant was in possession of an antibody specific for antigenic site A of RSV protein F. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 4 are indefinite in the recitation of "neutralizing antibody", the meaning of which has not been defined in the specification thus rendering the metes and bounds of the claims unclear.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1-4 and 21 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Tempest et al. (March, 1991).

Tempest et al. teach an anti-RSV protein F neutralizing antibody comprising 3 murine CDR regions on an antibody framework comprising human heavy and light chains. Further, the reference describes a human-murine chimeric antibody as being "useful in the management of this major childhood disease," (see particularly Abstract and Figure 2).

The reference teaching clearly anticipates the claimed invention.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-4, 6-7 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tempest et al. (1991) in view of Beeler et al. (1989)

Tempest has been discussed supra. The reference differs from the claimed invention only in that it does not teach humanized anti RSV antibodies specific for the A or C sites of protein F.

Beeler et al. teaches neutralizing anti RSV antibodies specific for the A or C sites of protein F. The reference further teaches that the A and C sites are preferred epitopes for antibody production because they are among the more highly conserved epitopes in RSV and therefore more likely to be found on various viral strains. Additionally, the reference teaches that RSV is one of the most important causes of respiratory infections in children worldwide and therefore an important pathogen against which to develop treatments (see entire document, particularly Table 3, page 2945 and Discussion, pages 2947-2948).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make neutralizing antibodies, as taught by Tempest et al., to the RSV protein F antigenic sites A and C, as taught by Beeler et al. One of ordinary skill in the art at the time the invention was made would have been motivated to produce said antibodies because Beeler et al. teach that the A and C sites are preferred epitopes for antibody production because they are among the more highly conserved epitopes in RSV and therefore more likely to be found on various viral strains. Additionally, the reference teaches that RSV is one of the most important causes of respiratory infections in children worldwide and therefore an important pathogen against which to develop treatments. Further, the human-murine chimeric antibody would be useful as a potential treatment for the "management of this major childhood disease," as taught by Tempest et al.

14. Claims 1-4, 6-7, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (1986) in view of Beeler et al. (1989).

Jones et al. teach the creation of human-mouse chimeric antibodies, specifically, the addition of mouse CDRs (at least one) to a human backbone of heavy and light chains. Further the reference teaches the value of said antibodies as potential treatments for various human diseases (see particularly Figure 2, page 524 and column 1, paragraph 2, page 525.)

The reference differs from the claimed invention in that it does not teach humanized antibodies to RSV and specifically, human-murine anti RSV antibodies for the A or C sites of protein F.

Beeler et al. has been discussed supra.

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make neutralizing human-mouse chimeric antibodies, as taught by Jones et al., to the RSV protein F antigenic sites A and C, as taught by Beeler et al. One of ordinary skill in the art at the time the invention was made would have been motivated to produce said antibodies because Beeler et al. teach that the A and C sites are preferred epitopes for antibody production because they are among the more highly conserved epitopes in RSV and therefore more likely to be found on various viral strains. Additionally, the reference teaches that RSV is one of the most important causes of respiratory infections in children worldwide and therefore an important pathogen against which to develop treatments, such as human-mouse chimeric antibodies, as taught by Jones et al.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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